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TITLE: Acustimulation for the Control of Chemotherapy-Induced Nausea in Breast Cancer Patients

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13. Abstract ***(Maximum 200 Words)*** *(abstract should contain no proprietary or confidential information)*

The current experiment examines the efficacy of acustimulation (mild electrical stimulation to an acupuncture point) to the Neiguan (P6) acupuncture point (located on the ventral surface of the wrist) in controlling chemotherapy-induced NV. It is a randomized three-arm clinical trial testing the usefulness of an acustimulation wrist band for the relief of chemotherapy-induced nausea and vomiting as an adjunct to standard 5-HT3 antiemetics. Patients who experienced nausea at their first treatment are eligible to participate. Patients in the two treatment groups (i.e., correct location: band worn on the inside of the wrist and sham location: band worn on the outside of the wrist) put on the acustimulation wrist band prior to the administration of chemotherapy and wear it for five days. The use of an active acustimulation band in the sham condition should effectively control for both the placebo effect and for any effect due to the release of endorphins and will therefore speak directly to the efficacy of acupuncture point stimulation. In addition, the experiment has a "no band" condition for additional comparisons. The study is proceeding on target with 40 of the targeted 107 patients having accrued thus far. We anticipate no problems in completing the study.

14. Subject Terms (keywords previously assigned to proposal abstract or terms which apply to this award)
acupressure, nausea and vomiting, intervention, cancer control, alternative medicine

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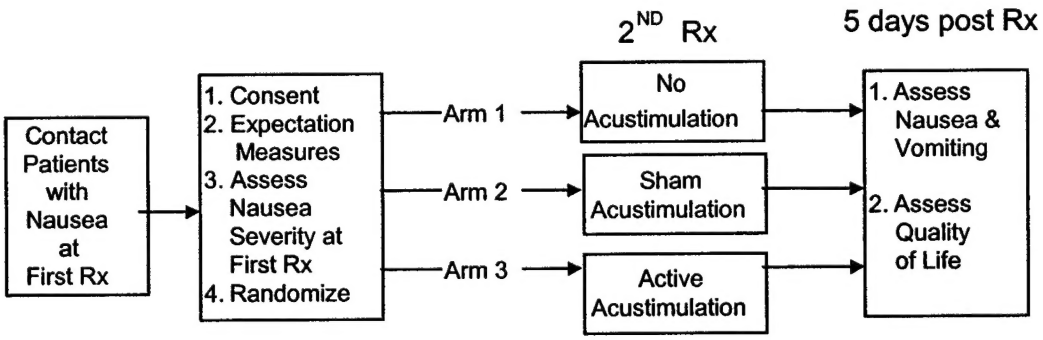
Introduction

The current experiment examines the efficacy of acustimulation (mild electrical stimulation to an acupuncture point) to the Neiguan (P6) acupuncture point (located on the ventral surface of the wrist) in controlling chemotherapy-induced NV. In traditional Chinese medicine, this acupuncture point is associated with NV relief. It is a randomized three-arm clinical trial testing the usefulness of an acustimulation wrist band for the relief of chemotherapy-induced nausea and vomiting as an adjunct to standard 5-HT_3 antiemetics. Patients who experienced nausea at their first treatment are eligible to participate. Patients in the two treatment groups (i.e., correct location: band worn on the inside of the wrist and sham location: band worn on the outside of the wrist) put on the acustimulation wrist band prior to the administration of chemotherapy and wear it for five days. The use of an active acustimulation band in the sham condition should effectively control for both the placebo effect and for any effect due to the release of endorphins and will therefore speak directly to the efficacy of acupuncture point stimulation. In addition, the experiment has a "no band" condition for additional comparisons.

STUDY SCHEMA



Hypothesis: Acustimulation to the Neiguan (P6) acupuncture point will be efficacious in controlling both delayed and acute chemotherapy-induced NV.

Primary Question: Can an acustimulation wrist band reduce the nausea and emesis that occurs on the day of chemotherapy treatment (acute) and that occurring on days 2 - 5 following treatment (delayed)?

Secondary Question: Is any effectiveness found for acustimulation related to patient expectancies of the effectiveness of the wrist band?

Body

Status of tasks listed in the Statement of Work:

Task 1: Month 1: Prepare treatment protocols and obtain IRB approval
Status: Completed, the study is approved and open to accrual at four locations. Two of the sites, Highland Hospital Cancer Center and Strong Memorial Hospital Cancer Center, are under the governing IRB at Strong Memorial Hospital. The remaining two, Rochester General Hospital Cancer Center and the Genesee Hospital Cancer Center, are under the governing IRB of VIA Health. As requested by Dr. Moore, a copy of the Genesee Hospital consent form is attached.

Task 2: Month 1: Present study protocol to clinic staffs at all study sites.
Status: Completed, the study has been presented to the clinic staff at four locations.

Task 3: Month 1: Prepare intervention materials and questionnaires.
Status: Completed. A copy of the one-page instruction sheet that we give patients and the study measures are attached.

Task 4: Months 1-34: Collect preliminary data on subjects screened for entry into the randomized study
Status: Ongoing. As part of our accrual process, we examine clinic schedules at the Highland Hospital Cancer Center, the Strong Memorial Hospital Cancer Center and the Rochester General Hospital Cancer Center in order to identify patients who have had one cycle of chemotherapy and who may be eligible for our study. We then contact the patient's oncologist for permission to talk to the patient about the study. At the Genesee Hospital, we rely on the nursing staff to identify potentially eligible patients.

Task 5: Months 1-34: Randomize eligible patients who have signed a consent form to group assignment (107 patients).
Status: Ongoing, 38 patients have been accrued and randomized to the protocol. In addition, data from two patient who were recruited prior to commencement of the experiment in order to test study procedures will be included in the analyses as no changes to study procedures were made.

Task 6: Months 1-34: Carry out the study.
Status: Ongoing

Task 7: Months 1-34: Monitor daily clinic schedules at all study sites (oncology departments in three Rochester hospitals) to insure timely accrual of subjects for the study.
Status: Ongoing

Task 8: Months 1-34: Review progress of study and address any problems as they arise.
Status: Ongoing, no problems have arisen.

Task 9: Months 1-34: Complete required annual reports.
Status: Ongoing

Task 10: Months 1-34: Edit, verify and input data as they are collected.
Status: Ongoing

Task 11: Months 35-36: Analyze results according to data analysis plan.
Status: No analyses have been made thus far

Task 12: Months 35-36: Write final report and complete fiscal accounting.
Status: Not applicable thus far

Key Research Accomplishments

Not applicable thus far

Reportable Outcomes

Not applicable thus far

Conclusions

Study is proceeding on target and we are encountering no unexpected problems.

Reliefband Positions

Inside wrist position: The center of band should be approximately 3 fingers width from the crease of the wrist.

Outside wrist position: The center of band should be approximately 2 fingers width from the crease of the wrist (where a watch is normally worn).

Instructions for using the Reliefband

1. Put a thin film of conductivity gel on the area of the wrist that will be touching the electrodes on the Reliefband. The area covered should be about the size of a quarter and in the middle of the wrist. The gel easily washes off and can be reapplied as necessary. Clean the electrodes with Kleenex whenever the gel is reapplied. Avoid using too much gel because this can reduce the electrical conductivity.

2. The Reliefband can be worn on either wrist or alternated between wrists as desired. Please do not change between the inside wrist and the outside wrist positions unless instructed to do so by the study manager.

3. Take care not to get the Reliefband wet.

4. You may adjust the intensity of the Reliefband using the dial to any of the five settings.

5. Please keep the Reliefband in a safe place during times you are not wearing it. It is very fragile and we have only a limited number of them. Please do not let any children handle it.

6. Call Joe Roscoe, Ph.D. or Sara Matteson, Psy.D. if you have questions about any aspect of the study or have problems with the Reliefband.

   Joe: 275-9962 office
   872-3562 home

   Sara: 275-2788 office

7. Call your doctor or nurse as you normally would if you have medically related problems or questions.

8. Take the Reliefband off if it is causing you any problems.

9. **Do not let anyone with a pacemaker wear the Reliefband.**

Patient I.D.

DATE ____/____/____
mo. day year

PATIENT EXPECTATION QUESTIONNAIRE

Please answer these questions prior to your chemotherapy treatment (but after the wrist band is in position for those patients randomized to wear a wrist band). **Answer the questions based on what you think will happen, not on what you hope will happen.**

1. How would you describe the NAUSEA at its worst after your first chemotherapy treatment?

- ○ Very mild or none at all
- ○ Mild
- ○ Moderate
- ○ Severe
- ○ Very severe
- ○ Intolerable

Here is a list of side effects that some patients have with some chemotherapies. For each side effect, please circle one number that best indicates your feelings:

		I am certain I will NOT have this				I am certain I WILL have this
2.	nausea	1	2	3	4	5
3.	vomiting	1	2	3	4	5
4.	fatique	1	2	3	4	5
5.	sleep problems	1	2	3	4	5

6. What do you think your level of NAUSEA will be at its worst after this treatment?

- ○ Very mild or none at all
- ○ Mild
- ○ Moderate
- ○ Severe
- ○ Very severe
- ○ Intolerable

7. What do side effects mean to you regarding the effect of the treatment on the disease?

- ○ Side effects mean that the chemotherapy is not working
- ○ Side effects mean that the chemotherapy is working
- ○ Side effects have no particular meaning

Answer the next question only if you have been randomized to wear a wrist band.

8. How effective do you think the wrist band you are wearing will be in helping to relieve or prevent treatment-related nausea and vomiting?

Not at all Effective				Very Effective
1	2	3	4	5

9887

46038

ACUPRESSURE STUDY U8199

O No band
O Outside of wrist
O Inside of wrist

DATE _____/_____/_____
mo. day year

Patient I.D.

ON STUDY DATA

Please answer the following questions about yourself.

1. Marital Status: O Married O Divorced O Separated O Single O Widowed

2. Gender: O Male O Female

3. Age [ ][ ]

4. Race: O White O Hispanic O Black O Asian O American`Indian O Other

5. What has your average daily alcohol consumption been over the past year?

   O less than 1 drink O 1 drink O 2 drinks O 3 drinks O 4 or more drinks

6. Are you susceptible to motion sickness? O yes O no

7. Did you experience pregnancy-related morning sickness? O yes O no O not applicable

8. Did you have morning sickness that included vomiting? O yes O no O not applicable

9. In general, are you more susceptible to **nausea** than your friends and family?

   O yes O no O about the same susceptibility

10. In general, are you more susceptible to **vomiting** than your friends and family?

    O yes O no O about the same susceptibility

11. Based upon what you know of yourself, how much chemotherapy-related **nausea** do you think you will have compared to other patients receiving the same treatments ?

    O more O less O about the same amount

12. Based upon what you know of yourself, how much chemotherapy-related **vomiting** do you think you will have compared to other patients receiving the same treatments ?

    O more O less O about the same amount

Patient I.D.

DATE ____/____/____
mo. day year

LOT - R

Please answer the following questions about yourself. Be as honest as you can throughout, and try not to let your response to one question influence your responses to other questions. There are no right or wrong answers.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1. In uncertain times, I usually expect the best.	○	○	○	○	○
2. It's easy for me to relax.	○	○	○	○	○
3. If something can go wrong for me, it will.	○	○	○	○	○
4. I'm always optimistic about my future.	○	○	○	○	○
5. I enjoy my friends a lot.	○	○	○	○	○
6. It's important for me to keep busy.	○	○	○	○	○
7. I hardly ever expect things to go my way.	○	○	○	○	○
8. I don't get upset too easily.	○	○	○	○	○
9. I rarely count on good things happening to me.	○	○	○	○	○
10. Overall, I expect more good things to happen to me than bad.	○	○	○	○	○

46145

Patient I.D.

DATE ____/____/____
mo. day year

FACT-G

Below is a list of statements that other people with your illness have said are "important." Circle one number per line to indicate how true each statement has been for you during the past 5 days.

During the past 5 days:	Not at all	A little bit	Somewhat	Quite a bit	Very Much
PHYSICAL WELL-BEING					
1) I have a lack of energy	1	2	3	4	5
2) I have nausea	1	2	3	4	5
3) I have trouble meeting the needs of my family	1	2	3	4	5
4) I have pain	1	2	3	4	5
5) I am bothered by the side effects of treatment	1	2	3	4	5
6) In general, I feel sick	1	2	3	4	5
7) I am forced to spend time in bed	1	2	3	4	5

8) How much does your PHYSICAL WELL-BEING effect your quality of life?

Not Much 1 2 3 4 5 6 7 8 9 10 **Very much so**

Patient I.D.

FACT-G (continued)

Below is a list of statements that other people with your illness have said are "important." Circle one number per line to indicate how true each statement has been for you during the past 5 days.

During the past 5 days:	Not at all	A little bit	Somewhat	Quite a bit	Very Much
SOCIAL/FAMILY WELL-BEING					
9) I feel distant from my friends	1	2	3	4	5
10) I get emotional.support frommy family	1	2	3	4	5
11) I get support from my friends and neighbors	1	2	3	4	5
12) My family has accepted my illness	1	2	3	4	5
13) Family communication about my illness is poor	1	2	3	4	5
(If you do not have a spouse/partner nor are sexually active, go to #16)					
14) I feel close to my partner (or main support).....	1	2	3	4	5
15) I am satisfied with my sex life	1	2	3	4	5

16) How much does your SOCIAL/FAMILYWELL-BEING effect your quality of life?

Not Much	1	2	3	4	5	6	7	8	9	10	Very much so

FACT-G (continued)

Below is a list of statements that other people with your illness have said are "important." Circle one number per line to indicate how true each statement has been for you during the past 5 days.

During the past 5 days:	Not at all	A little bit	Somewhat	Quite a bit	Very Much
RELATIONSHIP WITH DOCTOR					
17) I have confidence in my doctor(s)	1	2	3	4	5
18) My doctor is available to answer my questions	1	2	3	4	5

19) How much does your RELATIONSHIP WITH YOUR DOCTOR effect your quality of life?

Not Much 1 2 3 4 5 6 7 8 9 10 **Very much so**

During the past 5 days:	Not at all	A little bit	Somewhat	Quite a bit	Very Much
EMOTIONAL WELL-BEING					
20) I feel sad	1	2	3	4	5
21) I am proud of how I am coping with my illness	1	2	3	4	5
22) I am losing hope in the fight against my illness	1	2	3	4	5
23) I feel nervous	1	2	3	4	5
24) I worry about dying	1	2	3	4	5

25) How much does your EMOTIONALWELL-BEING effect your quality of life?

Not Much 1 2 3 4 5 6 7 8 9 10 **Very much so**

Patient I.D.

FACT-G (continued)

Below is a list of statements that other people with your illness have said are "important." Circle one number per line to indicate how true each statement has been for you during the past 5 days.

During the past 5 days:	Not at all	A little bit	Somewhat	Quite a bit	Very Much
FUNCTIONAL WELL-BEING					
26) I am able to work (include work in home)	1	2	3	4	5
27) My work (include work in home) is fulfilling	1	2	3	4	5
28) I am able to enjoy life "in the moment"	1	2	3	4	5
29) I have accepted my illness	1	2	3	4	5
30) I am sleeping well	1	2	3	4	5
31) I am enjoying my usual liesure activity pursuits	1	2	3	4	5
32) I am content with the quality of my life right now	1	2	3	4	5

33) How much does your FUNCTIONAL WELL-BEING effect your quality of life?

Not Much	1	2	3	4	5	6	7	8	9	10	Very much so

ACUPRESSURE STUDY **U8199**

48014

DATE COMPLETED____/____/____
mo.dayyear

Patient I.D.

FIVE-DAY RECORD OF NAUSEA AND VOMITING

Directions: Enter a number from 1 to 7 in each of the boxes that corresponds to how you felt at that time.

	Day of Treatment	1st Day Following Treatment	2nd Day Following Treatment	3rd Day Following Treatment	4th Day Following Treatment
	_____ (day of wk)	_____ (day of wk)	_____ (day of wk)	_____ (day of wk)	_____ (day of wk)
How nauseated did you feel? Morning					
Afternoon					
Evening					
Nighttime					

NAUSEA SCALE

1 2 3 4 5 6 7

Not at all Nauseated — Moderately Nauseated — Extremely Nauseated

Directions: Please tell us how many times you vomited.

How many times did you vomit? Enter "0" if none. Morning					
Afternoon					
Evening					
Nighttime					

VOMITING:
Indicate the actual number of times you vomited.

REV 7/6/00

FDHR 1

ACUPRESSURE STUDY **U8199**

48014

Patient I.D.

FIVE-DAY RECORD OF ANTI-NAUSEA MEDICATION

Please tell us how many and what types of anti-nausea medication that you took at home during the five days after your treatment. We are separating anti-nausea medications into 4 types. Please circle the medication name and fill in the boxes to tell us how many pills or suppositories of each type that you used during each portion of the day. Use the other box under type 4 for non-listed medications.

		Day of Treatment	1st Day Following Treatment	2nd Day Following Treatment	3rd Day Following Treatment	4th Day Following Treatment
		(day of wk)	(day of wk)	(day of wk)	(day of wk)	(day of wk)
How many pills or suppositories of **Type 1** did you take?	Morning					
	Afternoon					
	Evening					
	Nighttime					

Type 1

Granisetron (Kytril)
Ondansetron (Zofran)
Mesaylate (Anzemet
Tropisetron (Navoban)

How many pills or suppositories of **Type 2** did you take?	Morning					
	Afternoon					
	Evening					
	Nighttime					

Type 2

Prochlorperazine (Compazine)

48014

Patient I.D.

FIVE-DAY RECORD OF ANTI-NAUSEA MEDICATION (Cont'd.)

Please tell us how many and what types of anti-nausea medication that you took at home during the five days after your treatment. We are separating anti-nausea medications into 4 types. Please circle the medication name and fill in the boxes to tell us how many pills or suppositories of each type that you used during each portion of the day. Use the other box under type 4 for non-listed medications.

		Day of Treatment	1st Day Following Treatment	2nd Day Following Treatment	3rd Day Following Treatment	4th Day Following Treatment
		(day of wk)	(day of wk)	(day of wk)	(day of wk)	(day of wk)
How many pills or suppositories of **Type 3** did you take?	Morning					
	Afternoon					
	Evening					
	Nighttime					

Type 3

Dexamethasone (Decadron)

How many pills or suppositories of **Type 4** did you take?	Morning					
	Afternoon					
	Evening					
	Nighttime					

Type 4

Metochlopramide (Reglan)

Other _____
(please give name)

48014

Patient I.D.

FIVE-DAY RECORD (Supplement)

Complete this next section only if you wore the wrist band for this treatment. Please answer these questions on the fourth day following your treatment.

1. How useful do you think the wrist band was in reducing NAUSEA?

   o Very
   o Somewhat
   o Works a little
   o Doesn't seem to help

2. How useful do you think the wrist band was in reducing VOMITING?

   o Very
   o Somewhat
   o Works a little
   o Doesn't seem to help

3. How many hours did you wear the wrist band?

   o less than 1 o 1-5 o 5-24 o 24-48 o more than 48

4. Based upon your experience with the wrist band at this treatment, would you recommend it to other patients receiving the same chemotherapy?

Strongly Do Not Recommend				Highly Recommend
1	2	3	4	5

viaHealth
The Genesee
Hospital

224 Alexander Street
Rochester, NY 14607-4055

716 922 6000

Acustimulation for the Control of Chemotherapy-Induced Nausea in Breast Cancer Patients (U8199)

Principal Investigators:

Peter Bushunow, MD **Joseph Roscoe, Ph.D.**
Gary Morrow, Ph.D.

CONSENT FORM

Introduction

This consent form describes a research study and what you may expect if you decide to participate. You are encouraged to read this consent form carefully and to ask the person who presents it any further questions you may have before making your decision whether or not to participate.

This study is being offered at the second treatment to cancer patients treated with chemotherapy who experienced either nausea or vomiting after their first treatment.

This form describes the known possible risks and benefits and describes what other choices for care or service are available to you if you do not wish to be in the study. You are completely free to choose whether or not to participate in this study.

Purpose of the Study

We are studying the effectiveness of acustimulation (electrical stimulation to an acupuncture point) when combined with normal antiemetics (anti-vomiting drugs) to more completely control nausea and vomiting in patients receiving chemotherapy. We also want to see whether there is a relationship between how much nausea and vomiting people expect they will have and the amount they actually experience. A total of 107 subjects are expected to take part in this study.

_____ _____
Witness Initials Patient Initials

Description of Procedures

It is not clear at the present time which of the three options in this program is more effective. If you agree to participate in this study, you will be assigned by random selection (like flipping a coin) to one of the three following treatment groups for this chemotherapy treatment only.

Group 1. Participants will receive whatever anti nausea drugs their doctor normally prescribes.

Group 2. Participants will receive whatever anti nausea drugs their doctor normally prescribes and will also receive a wrist band that gives mild electrical stimulation to an acupuncture point on the **outside** of the wrist. (Note: You will be taught how to adjust the intensity of the electrical stimulation before putting on the wrist band. You will be able to set the stimulation to a barely noticeable level or turn it off completely.)

Group 3. Participants will receive whatever anti nausea drugs their doctor normally prescribes and will also receive a wrist band that gives mild electrical stimulation to an acupuncture point on the **inside** of the wrist. (Note: You will be taught how to adjust the intensity of the electrical stimulation before putting on the wrist band. You will be able to set the stimulation to a barely noticeable level or turn it off completely.)

If you are assigned to either group 2 or group 3, you will be asked to put on the wrist band(s) before you receive chemotherapy and to wear it for five days, taking it off only to avoid immersing it in water.

Just before your treatment begins, you will be asked to complete paper and pencil questionnaires that tell about your expectations for treatment-related side effects and how you feel about your illness. You will also be asked to complete a record of your degree of nausea and vomiting after your treatment and a quality of life measure. Filling out the questionnaires will take approximately 20 minutes. You will be given a stamped addressed envelope in which to mail the completed forms back.

Notification of Results

We will send you a letter when the study is complete (around June 1, 2003) letting you know what the results of this study are and what other researchers have learned concerning acustimulation and the most effective location for the acustimulation device.

Risks & Discomforts

The acustimulation wrist band may not be worn if you have a cardiac pacemaker in order to avoid any possible interference with the pacemaker signal. Prolonged use of the

acustimulation wrist band may aggravate sensitive skin. You may alternate wrists, reduce the intensity of the stimulation, or remove the band if problems with skin irritation arise. Mild tingling may be felt in the fingers or elsewhere in the hand when the stimulation intensity is set to a high level. There is no evidence that this sensation is harmful and you can stop it by lowering the stimulation intensity or removing the band.

The device should be worn on the wrist opposite a hand in which an IV is placed; the device should not be immersed in water; the device may interfere with monitoring equipment (e.g., ECG monitors); and it should be kept out of reach the of children since the dial may become a choking hazard if it is removed.

Benefits of Participation

It is not possible to predict whether you will receive any personal benefit from participating in this research study.

Voluntary Participation

Participation in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason, without risking loss of present or future care you would otherwise expect to receive. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

New Findings

You will be informed of any new finding which may affect your decision to continue your participation in this research study.

Circumstances for Leaving the Study

If new scientific developments occur that indicate the treatment is not in your best interest, we will let you know.

Costs

No compensation for participation will be given. The wrist band will be provided free of charge, but you need to return it to us when the study is over. There are no extra visits or tests associated with this study. All charges for your treatments and tests are the responsibility of you and your insurance company whether or not you participate in this study.

Witness Initials _____ Patient Initials _____

Confidentiality of Records

A record of your progress while on the study will be kept in a confidential file at the University of Rochester Cancer Center. While we will make every effort to maintain your confidentiality, it cannot be absolutely guaranteed. Medical records which identify you and the consent form signed by you, may be inspected by the ViaHealth Clinical Investigations Committee, government regulatory agencies and/or represenatives of the Uviversity of Rochester Human Subjects Review Board. In addition, because the Department of the Defense is the sponsor of this study, representatives of the U.S. Army Medical Research and Materiel Command are eligible to review research records as part of their responsibility to protect human subjects in research. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

Contact Persons

For more information concerning the research and research-related risks or injury, your physicians and/or oncology nurse can be contacted (716) 922-8800. Contact Joseph Roscoe the study coordinator at (716) 275-9962 for non-medical questions concerning this research. For more information regarding patients' rights in research studies, please call Administration for the Clinical Investigation Committee at 716-922-5640.

Signatures/Dates

I have read the contents of this consent form, asked questions, and received answers concerning areas I did not understand. I give my consent to participate in this study by signing this form. I will receive a copy of this form for my records.

Subject Signature	Print Name	Date

Permanent address of subject

Witness Signature	Print Name	Date

Physician Investigator - I have verbally presented the consent form to the subject and have answered questions completely.

P.I. Signature	Date